DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 25, 2014

Demetech Corporation
Mr. Anthony J. Dimercurio
Vice President of Regulatory Affairs/Quality Assurance
14175 Northwest 60th Avenue
Miami Lakes, Florida 33014

Re: K141007
Trade/Device Name: Demetech Non-Absorbable Stainless Steel Surgical Suture
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: Class II
Product Code: GAQ
Dated: August 29, 2014
Received: September 4, 2014

Dear Mr. Dimercurio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6
Indications for Use Statement

Indication for use

Device Name: Demetech Non-Absorbable Stainless Steel Surgical Suture.

Indication for Use:

"DemeSTEEL" is a stainless steel suture composed of 316L stainless steel with or without needles attached, and is intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, sternal closure and certain orthopedic procedures, including cerclage and tendon repair.

Prescription Use ____"X"____ And / Or Over the-Counter Use_____
(Part 21 CFR 801; Subpart D) (21 CFR 801; Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DemeTECH®

Section 7 - 510(k) Summary

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Demetech Sutures to those of the legally marked predicate devices listed.

A. Applicant: Demetech Corporation,
14175 NW 60th Ave.
Miami Lakes FL. 33014 USA

B. Contact Person: Anthony. J. Dimercurio
E-mail: tony@demetech.us
Phone # 305-824-1048 Ext 115

C. Date Prepared: April 17th, 2014

Trade Name: DemeSTEEL Stainless Steel Non-Absorbable Suture

Common Name: Stainless Steel Suture

Classification Name: Suture, non-absorbable, steel, monofilament and multifilament, sterile

D. Device Classification:

FDA Class: Class II

Regulation Number: 878.4495 Stainless steel suture

Code: GAQ

E. Predicate Devices: Demetech's Stainless Steel Non-absorbable Suture (DemeSTEEL) is substantially equivalent to these predicate devices:

- Look Inc., 316L Stainless Steel surgical sutures reference 510K number K933686, Look Inc. Lonnie Abbott Ind. Blvd. Ada OK 74820
- Lukens Medical Corp. Stainless Steel Suture, reference 510K number K930940 via the Lahr Group Mahwah, NJ.
- Ethicon's, Stainless Steel Suture reference 510K number, K931271, Ethicon Inc. Somerville NJ.

F. Device Description:

Demetech's DemeSTEEL is a Monofilament and/or Multifilament Non-absorbable surgical suture composed of 316L Stainless Steel and supplied with and without needles affixed to the sutures. Demetech's DemeSTEEL Surgical Suture meets the requirements established by the United States Pharmacopeia (U.S.P.) for non-absorbable surgical sutures. DemeSTEEL Stainless Steel sutures are composed of 316L stainless steel conforming to the FDA recognized ASTM Standard F138 Grade 2 "Stainless steel bar and wire for surgical implants".

G. Intended Use:

DemeSTEEL is a stainless steel suture composed of 316L stainless steel, with or without needles attached, and is intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, sternal closure and certain orthopedic procedures, including cerclage and tendon repair.

H. Non-Clinical Tests Performed:

Non-clinical testing was conducted on the device to prove conformance to the requirements of USP standards and to demonstrate substantial equivalence to the predicate devices. Physical properties and functionality testing assures the device conforms with suture diameter, suture length, knot pull and/or straight pull tensile strength, needle attachment strength, and sterility, methods outlined in USP 36. Demetech's DemeSTEEL Sutures meets all In-house and United States Pharmacopeia specifications and is equivalent to the above mentioned predicate devices.

DemeSTEEL is manufactured with 316L Stainless Steel, selected based on known biocompatibility and established history of use in the medical device industry for implantable devices, and is identical and equivalent to the Stainless Steel 316L used in the predicate devices listed above. Biocompatibility testing performed on 316L stainless steel sutures included within this submission, the following: Cytotoxicity, Acute Toxicity, Skin Sensitization, Mutagenicity, Carcinogenicity and Reproductive Toxicity.

COMPARISON TABLE DEMETECH DemeSTEEL TO PREDICATE DEVICES

Comparison Items	Demetech Stainless Steel Suture	Look 316L Stainless Steel Suture	Lukens Medical Stainless Steel Suture	Ethicon Stainless Steel Suture
DemeSTEEL Stainless Steel suture us a Non-Absorbable surgical suture. It is a sterile flexible Monofilament or Multifilament thread, composed of 316L Steel	≡	Same	Same	Same
DemeSTEEL suture is un-dyed silver metallic and is un-coated.	≡	Same	Same	Same

DemeSTEEL is a stainless steel suture composed of 316L stainless steel, is intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, sternal closure and certain orthopedic procedures, including cerclage and tendon repair	≡	Same	Same	Same
DemeSTEEL suture is supplied for single use only	≡	Same	Same	Same
DemeSTEEL suture is sterilized by Gamma Irradiation Sterilization	≡	Same	Same	Same
DemeSTEEL suture is packaged in the same or equivalent manner, and has the same or equivalent labeling claims as that of the predicate devices including indications, warnings, cautions and precautions	≡	Same	Same	Same
DemeSTEEL suture meets or exceeds the performance requirements for "Non-Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia.	≡	Same	Same	Same
DemeSTEEL suture meets the performance requirements for "Diameter", Section <661> as defined in the United States Pharmacopeia.	≡	Same	Same	Same
DemeSTEEL suture meets or exceeds the performance requirements defined in the United States Pharmacopeia for "Tensile Strength" <881>	≡	Same	Same	Same
DemeSTEEL suture meets or exceeds the performance requirements defined in the United States Pharmacopeia and the current edition USP for "Needle Attachment" < 871 >	≡	Same	Same	Same
DemeSTEEL suture meets the performance requirements defined in the United States Pharmacopeia for "Suture Length Requirement" (95% of stated label length)	≡	Same	Same	Same
DemeSTEEL suture meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. for sterility and per ISO-11137	≡	Same	Same	Same
DemeSTEEL Suture is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and Current edition of USP.	≡	Same	Same	Same

DemeSTEEL Meets the requirements of ASTM F138-13a-- Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants UNS S31673	≡	Same	Same	Same
DemeSteel Stainless Steel 316L meets the Classification requirements in 21CFR section 878.4495, Identification A stainless steel suture, needled or without needles, is a non-absorbable suture composed of 316L stainless steel.	≡	Same	Same	Same

Note: "≡"; Signifies the Demetech statement is identical to each of the predicate devices.

I. Clinical Tests Performed:

No clinical trials were conducted or required for this submission

J. Conclusion:

DemeSteel Sutures are composed of the same suture materials, "an implantable surgical grade 316L Stainless Steel suture", as are the predicated devices, having the same design, being a sterile, flexible, Monofilament and/or Multifilament threads meeting all the requirements of the United States Pharmacopeia. Demetech's DemeSteel Sutures are manufactured in the same manner as the predicate devices, being composed of a monofilament or multifilament 316L stainless steel thread or wire, with or without attached needles. Our supplier produces the treads or wire, in operations considered standard in the industry to manufacture and form the stainless steel suture material. Our vendor supplies to Demetech the same stainless steel grade 316L suture materials as it does to other suture manufacturers, including some of those listed as predicates in this submission.